

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION**

EMBRY WAYNE HESTER, as
PERSONAL REPRESENTATIVE
of the ESTATE OF MARTHA
CAROLYN HESTER,

Plaintiff,

v.

MERCK & CO., INC., a New Jersey
Corporation; PFIZER INC., a Delaware
Corporation; PHARMACIA & UPJOHN
COMPANY, a Delaware Company;
PHARMACIA CORPORATION, 1933
MONSANTO, a Delaware Corporation;
G.D. SEARLE, LLC., a Delaware
Corporation,

Defendants.

Case No. 2:06CV242-MHT

**ANSWER AND DEFENSES OF ANSWERING DEFENDANTS TO
PLAINTIFFS' COMPLAINT**

Defendants Pfizer Inc. ("Pfizer"), Pharmacia & Upjohn Company LLC ("Upjohn") (improperly captioned in Plaintiffs' Complaint as "Pharmacia & Upjohn Company"), Pharmacia Corporation ("Pharmacia") and G.D. Searle LLC ("Searle") (improperly captioned in Plaintiff's Complaint as "G.D. Searle, LLC"), (collectively the "Answering Defendants") hereby answer Plaintiff's Complaint in this action and state as follows:

PRELIMINARY STATEMENT

The Complaint does not state when Plaintiff's decedent was prescribed or used Celebrex® and, as such, this Answer can only be drafted generally and without reference to a specific period in time. Answering Defendants reserve the right to amend this Answer if or when discovery reveals the time period in which the Plaintiffs were prescribed and used Celebrex®.

To the extent any allegations in Plaintiff's Complaint refer to Vioxx® and/or Merck & Co., Inc. ("Merck"), such allegations are not directed to Answering Defendants and no answer is required of Answering Defendants. To the extent an answer is deemed required, Answering Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations and therefore deny the same.

This preliminary statement is incorporated by reference in its entirety in response to each and every paragraph of Plaintiffs' Complaint.

**ANSWERING:
STATEMENT OF THE PARTIES**

1. Answering Paragraph 1, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in Paragraph 1, and therefore deny the same.

2. Paragraph 2 makes no allegations against Answering Defendants; accordingly, no answer is required.

3. Answering Paragraph 3, Answering Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and is registered to do business in Alabama. Answering Defendants admit that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 3.

4. Answering Paragraph 4, Defendants admit that Pharmacia & Upjohn Company LLC is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation, which is a corporation existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey. Except as admitted herein, Defendants deny the allegations of Paragraph 4.

5. Answering Paragraph 5, Answering Defendants admit that Pharmacia Corporation (“Pharmacia”) is a corporation existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey, and is registered to do business in Alabama. Answering Defendants admit that, during certain period(s) of time, Pharmacia marketed the prescription drug Celebrex® in

the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 5.

6. Answering Paragraph 6, Answering Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois and that it is registered to do business in Alabama. The Answering Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 6.

**ANSWERING:
FACTUAL ALLEGATIONS**

7. Answering Paragraph 7 as it relates to Answering Defendants, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in sentence 1, and therefore deny the same. As to sentence 2, the allegations are not directed towards Answering Defendants, and, therefore, no responsive pleading is required. As to sentence 3, Answering Defendants admit that Celebrex® is a selective COX-2 inhibitor.

Answering Defendants admit that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Defendants deny the allegations of Paragraph 7 that relate to Answering Defendants. The allegations relating to Vioxx® and/or Merck are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

8. Answering Paragraph 8 as it relates to Answering Defendants, Answering Defendants deny that they collectively distributed and sold Celebrex® to consumers. Answering Defendants further deny prescribing Celebrex® to consumers as no named defendants are licensed physicians. Answering Defendants incorporate their responses to Paragraphs 3-7. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 8 that relate to Answering Defendants.

9. Answering Paragraph 9 as it relates to Answering Defendants, Answering Defendants incorporate their responses to Paragraphs 3-7. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 9 that relate to

Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

10. Answering Paragraph 10, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

11. Answering Paragraph 11, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

12. Answering Paragraph 12, Answering Defendants deny the allegations contained therein.

13. Answering Paragraph 13, Answering Defendants deny the allegations contained therein.

14. Answering Paragraph 14, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

15. Answering Paragraph 15, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations

relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

**ANSWERING:
COUNT I:
NEGLIGENCE**

16. Answering Paragraph 16, Answering Defendants incorporate their responses to Paragraphs 1-15 as if set forth fully herein.

17. Answering Paragraph 17 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

18. Answering Paragraph 18, as it relates to Answering Defendants, Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 18 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

19. Answering Paragraph 19 as it relates to Answering Defendants, inclusive of any subpart thereto, Answering Defendants deny the allegations

contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

20. Answering Paragraph 20 as it relates to Answering Defendants, Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

21. Answering Paragraph 21 as it relates to Answering Defendants, Answering Defendants admit that they have such duties as are imposed by applicable law. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 21 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

**ANSWERING:
COUNT II:
NEGLIGENT FAILURE TO WARN**

22. Answering Paragraph 22, Answering Defendants incorporate their responses to Paragraphs 1-21 as if set forth fully herein.

23. Answering Paragraph 23 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

24. Answering Paragraph 24 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

25. Answering Paragraph 25 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

26. Answering Paragraph 26 as it relates to Answering Defendants, inclusive of all subparts thereto, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

**ANSWERING:
COUNT III:
MISREPRESENTATION AND SUPPRESSION**

27. Answering Paragraph 27, Answering Defendants incorporate their responses to Paragraphs 1-26 as if set forth fully herein.

28. Answering Paragraph 28 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

29. Answering Paragraph 29 as it relates to Answering Defendants, inclusive of all subparts thereto, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

30. Answering Paragraph 30 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

31. Answering Paragraph 31 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to

Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

32. Answering Paragraph 32 as it relates to Answering Defendants, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiff's knowledge and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 32 that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants, and therefore, no responsive pleading is required.

33. Answering Paragraph 33 as it relates to Answering Defendants, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiff's knowledge and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 33 that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants, and therefore, no responsive pleading is required.

34. Answering Paragraph 34 as it relates to Answering Defendants, Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by

applicable law. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 34 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

35. Answering Paragraph 35 as it relates to Answering Defendants, Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiffs' ingestion of any drug and therefore deny the same. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 35 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

36. Answering Paragraph 36 as it relates to Answering Defendants, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding reliance by health care professionals and consumers and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 36 that are related to Answering Defendants. The allegations relating to Vioxx® are not

directed towards Answering Defendants, and therefore, no responsive pleading is required.

37. Answering Paragraph 37 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants, and therefore, no responsive pleading is required.

**ANSWERING:
COUNT IV:
BREACH OF WARRANTY**

38. Answering Paragraph 38, Answering Defendants incorporate their responses to Paragraphs 1-37 as if set forth fully herein.

39. Answering Paragraph 39 as it relates to Answering Defendants, Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 39 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

40. Answering Paragraph 40 as it relates to Answering Defendants, Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Answering

Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiffs' knowledge and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 40 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

41. Answering Paragraph 41 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

42. Answering Paragraph 42 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

43. Answering Paragraph 43 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

ANSWERING:

COUNT V:
BREACH OF EXPRESS WARRANTY

44. Answering Paragraph 44, Answering Defendants incorporate their responses to Paragraphs 1-44 as if set forth fully herein.

45. Answering Paragraph 45 as it relates to Answering Defendants, Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 45 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

46. Answering Paragraph 46 as it relates to Answering Defendants, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiffs' reliance and therefore deny the same. Except as admitted herein, Answering Defendants deny the allegations contained in Paragraph 46 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and therefore, no responsive pleading is required.

47. Answering Paragraph 47 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to

Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

**ANSWERING:
COUNT VI:
FRAUD**

48. Answering Paragraph 48, Answering Defendants incorporate their responses to Paragraphs 1-47 as if set forth fully herein.

49. Answering Paragraph 49 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

50. Answering Paragraph 50 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

51. Answering Paragraph 51 as it relates to Answering Defendants, Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required,

Answering Defendants admit that they have such duties as are imposed by applicable law. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 51 that are related to Answering Defendants. The allegations relating to Merck and/or Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

**ANSWERING:
COUNT VII:
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE
(AEMLD)**

52. Answering Paragraph 52, Answering Defendants incorporate their responses to Paragraphs 1-51 as if set forth fully herein.

53. Answering Paragraph 53 as it relates to Answering Defendants, Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiffs' alleged use of Celebrex® and therefore deny the same. Answering Defendants incorporate their response to Paragraphs 3-7. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 53 that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants, and, therefore, no responsive pleading is required.

54. Answering Paragraph 54 as it relates to Answering Defendants, Answering Defendants deny the allegations contained therein that are related to Answering Defendants. The allegations relating to Vioxx® are not directed towards Answering Defendants and, therefore, no responsive pleading is required.

**ANSWERING:
DEMAND FOR RELIEF**

Answering Defendants deny that the Plaintiffs are entitled to any of the relief demanded in the unnumbered WHEREFORE clause and all its subparts.

DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Answering Defendants in this matter. Answering Defendants therefore assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Answering Defendants will withdraw any of these defenses as may be appropriate.

1. Plaintiff's Complaint fails to state a claim against Answering Defendants upon which relief can be granted.
2. Plaintiffs' claims are barred by the applicable statute of limitations and/or repose or by the equitable doctrines of laches, waiver and estoppel.
3. Plaintiffs' decedent's injuries and damages, if any, were solely caused by the acts or omissions, abuse or misuse, negligence or fault or otherwise, of third

persons or parties over whom Answering Defendants had no control or right to control and whose actions are not, therefore, imputable to Answering Defendants.

4. Answering Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff or Plaintiff's decedent herein. Additionally, as a manufacturer and not a seller, Answering Defendants are not subject to liability for implied warranties without privity, i.e., proof of direct and specific transactions between Plaintiff's decedent and Answering Defendants. If any such warranties were made, whether express or implied, which Answering Defendants specifically deny, then Plaintiff's decedent failed to give timely notice of any breach thereof as required under Ala. Code § 7-2-607.

5. Plaintiff's decedent's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff's decedent or those acting at the direction or control of Plaintiff's decedent, whose contributory negligence or fault is sufficient to bar any recovery by Plaintiff.

6. Plaintiff's decedent's injuries, if any, were due to an unforeseeable idiosyncratic reaction of Plaintiff's decedent, or by an unforeseeable disease or illness, unavoidable accident, or pre-existing and/or unrelated conditions, or natural courses of conditions of Plaintiffs, and were independent of any conduct by Answering Defendants.

7. Plaintiff's decedent failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

8. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

9. Celebrex® is safe when used as directed, was suitable for the purpose for which it was intended, was distributed with adequate and sufficient warnings and Answering Defendants reasonably assumed that their warnings would be read and heeded; therefore, Celebrex® is not and was not defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A, Comment j.

10. As a prescription pharmaceutical, Celebrex® falls within the ambit of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and Drug Administration. Accordingly, Plaintiff's claims have been preempted under the Supremacy Clause of the U.S. Constitution.

11. Both Celebrex® and Answering Defendants' actions conformed to the state-of-the-art medical and scientific knowledge at all times relevant to this lawsuit and Celebrex® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

12. Plaintiff's claims are barred by assumption of the risk.

13. Plaintiff's claims are barred in whole or in part because Celebrex® "provides net benefits for a class of patients" within the meaning of the Restatement (Third) of Torts: Product Liability § 6, Comment f.

14. Plaintiff's claims are barred in whole or in part by the "learned intermediary" doctrine.

15. The imposition of punitive damages pursuant to current Alabama law violates the Due Process and Equal Protection provisions of U.S. Const. Amend. XIV; to wit, these Answering Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Alabama's current laws regarding punitive damages do not serve a rational or legitimate state interest.

16. Plaintiffs' claims for punitive damages violate these Answering Defendants' rights under the Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendment of the Constitution of the United States of America and Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Alabama.

17. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution and decisions of the United States Supreme Court including, but not limited to: *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper*

Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). Further, Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damages, which arise under the Constitution of Alabama, Alabama state statutes, and the decision of Alabama state courts.

18. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

19. Plaintiff's claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

20. If Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by operation of nature or other supervening or intervening conduct of persons other than Answering Defendants, and for whose conduct Answering Defendants are not responsible, or with whom Answering Defendants have no legal relation or legal duty to control.

21. If Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by the unforeseeable alterations, improper handling, or other unforeseeable misuse of Celebrex® by persons other than Answering Defendants or persons acting on their behalf.

22. Plaintiff's claims are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff's decedent.

23. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Answering Defendants' rights under the United States Constitution.

24. Plaintiff's claims are barred, in whole or in part, because Plaintiff and Plaintiff's decedent did not incur any ascertainable loss as a result of Answering Defendants' conduct.

25. Plaintiff's claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling packaging, and any advertising of Celebrex® complied with the applicable codes, standards and regulations established, adopted or promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

26. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Celebrex® were not false or

misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

27. Plaintiff's claims must be dismissed because Plaintiff's decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

28. Plaintiff's claims are barred because the utility of Celebrex® outweighed its respective risks.

29. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

30. Plaintiff's and Plaintiff's decedent's damages, if any, are barred or limited by the payments received from collateral sources.

31. The liability of Answering Defendants, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Answering Defendants seek an adjudication of the percentage of fault of the claimant and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

32. Answering Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other defendant or other person or entity.

33. Plaintiff's claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, the regulations promulgated thereunder, and the United States Constitution, Article IV, clause 2.

34. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act.

35. Plaintiff's claims are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

36. Plaintiff's claims are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the

Supremacy Clause of the United States Constitution, Article IV, clause 2, and the laws of the United States.

37. If Plaintiff's decedent sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Answering Defendants and over whom Answering Defendants had no control and for whom Answering Defendants may not be held accountable.

38. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

JURY DEMAND

Answering Defendants demand a trial by jury on all issues so triable.

WHEREFORE, Answering Defendants respectfully request that this action be dismissed with prejudice and that they be awarded their costs and any other forms of relief to which they may be entitled.



Lawrence B. Clark
Jason Asbell

OF COUNSEL:


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Certificate of Service

I hereby certify that on April ⁷~~6~~, 2006, a copy of the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to the party indicated on the electronic filing receipt listed below who may access this filing through the Court's electronic filing system.

Tom Dutton
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Of Counsel